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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. | | | | | | | | | | | | |
|---|---------------|----------------------|---|------------------|----------|--|-----------------------|--|----------|--------------|------|--|-----------|---------------|------------|-------|
| 10/561,220 | 04/04/2006 | Gil Ronen | 30698 | 2247 | | | | | | | | | | | | |
| 7590 Martin Moynihah Prtsi Inc PO Box 16446 Arlington, VA 22215 | | 01/30/2008 | <table border="1"><tr><td colspan="2">EXAMINER</td></tr><tr><td colspan="2">WORLEY, CATHY KINGDON</td></tr><tr><td>ART UNIT</td><td>PAPER NUMBER</td></tr><tr><td colspan="2">1638</td></tr><tr><td>MAIL DATE</td><td>DELIVERY MODE</td></tr><tr><td>01/30/2008</td><td>PAPER</td></tr></table> | | EXAMINER | | WORLEY, CATHY KINGDON | | ART UNIT | PAPER NUMBER | 1638 | | MAIL DATE | DELIVERY MODE | 01/30/2008 | PAPER |
| EXAMINER | | | | | | | | | | | | | | | | |
| WORLEY, CATHY KINGDON | | | | | | | | | | | | | | | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|-------------------------------|------------------------------|--|
| Office Action Summary | Application No. 10/561,220 | Applicant(s) RONEN ET AL. | |
| | Examiner Cathy K. Worley | Art Unit 1638 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 November 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 6-52 is/are pending in the application.
- 4a) Of the above claim(s) 9-52 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 6-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 December 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>10/23/06</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Restriction/Election

1. In response to the communication received on Nov. 19, 2007, from Martin Moynihan, the election of groups I-XV, claims 1-4 and 6-8 as they relate to SEQ ID NO:23, is acknowledged. Because applicant did not distinctly and specifically point out any errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Applicant is advised to amend the claims to read only on the elected invention of SEQ ID NO:23. This restriction requirement is **MADE FINAL**.

The Applicant is reminded that the examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability

including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained.

Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Petition to Accept Color Photographs

2. The Office received a petition to accept color photographs in the papers filed on Dec. 19, 2005. This petition has been approved and the color photographs are accepted.

/Anne Marie Grunberg/ Supervisory Patent Examiner, art unit 1638

Information Disclosure Statement

3. The information disclosure statement (IDS) submitted on Dec. 23, 2006 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner. The page numbers on the IDS were not correct; therefore, the Examiner corrected the page numbers in addition to initialing, signing, and dating the IDS.

4. The listing of references in the specification on pages 52-54 is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Sequence Rule Compliance

5. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. § 1.821-1.825 because the Applicant has not provided a

statement that the computer-readable format and the hard copy of the sequence listing are identical. The Applicant is advised to supply the appropriate statement.

Specification

6. The specification is objected to because it contains embedded hyperlinks and/or other forms of browser-executable code. On page 17, line 32; page 18, line 1; page 19, lines 14 and 17; page 29, line 11; and page 31, lines 12-13 there are embedded links. Applicant is required to delete the embedded hyperlinks and/or other forms of browser-executable code. See MPEP 608.01.

7. The specification is objected to because the Brief Description of the Drawings does not clearly describe each of the separate panels for Figures 1, 4, and 6. The Applicant is advised to amend the Brief Descriptions of the Drawings to include separate descriptions of each of panels A-H for figure 1, and each of panels A-C for Figure 4, and each of panels A-D for Figure 6.

8. The use of the following trademarks has been noted in this application: RNEASY and DNEASY. They should be written in all capital letters wherever they appear; or alternatively, they should be denoted with the registered trademark symbol, ®, and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

9. The abstract of the disclosure is objected to because it is not sufficiently descriptive of the elected invention. The abstract should be between 50 and 150 words in length and it should specify that the invention is a promoter from cotton that is active in trichomes. Correction is requested. See MPEP § 608.01(b).

Claim Objections

10. Claim 3 is objected to because of the following informalities: it is grammatically incorrect. The Applicant is advised to replace "comprising" with - - comprises - - . Appropriate correction is requested.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

11. Claim 7 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The current recitation in claim 7

encompasses transgenic human cells, and therefore it does not constitute statutory subject matter. The Applicant is advised to amend the claim by inserting - - , wherein said cell is a plant or bacterial cell - - at the end of the claim. This amendment would overcome this rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 1-3, 7, and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Larkin et al (Plant Cell (1993) Vol. 5, pp. 1739-1748).

The claims are drawn to an isolated polynucleotide comprising "a" nucleic acid sequence as set forth in SEQ ID NO:23, and to a construct, transgenic cell, and transgenic plant comprising said polynucleotide. The use of the article "a" renders this recitation includes of fragments of SEQ ID NO:23 as small as dinucleotides.

The GL1 promoter taught by Larkin et al comprises an EcoRV restriction site (see page 1747, left column) which consists of "gatatc". Therefore the GL1 promoter comprises the sequence "gatat", and "gatat" is "a" nucleic acid sequence as set forth in SEQ ID NO:23 (see bases 823-827 of SEQ ID NO:23). Larkin et al teach

constructs comprising this GL1 promoter operably linked to the GUS coding sequence (see page 1747, left column), and they teach Arabidopsis plants transformed with this construct (see paragraph bridging left and right columns on page 1747). The transgenic Arabidopsis plants inherently comprise transgenic cells comprising said construct.

13. Claims 1-4 and 6-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Wan et al (JBC (1996) Vol. 271, pp. 31227-31233) as evidenced by SP6 promoter sequencing primer catalog page from Fermentas Life Sciences (2000).

The claims are drawn to an isolated polynucleotide comprising "a" nucleic acid sequence as set forth in SEQ ID NO:23, and to a construct, transgenic cell, and transgenic plant comprising said polynucleotide, and to a nucleic acid construct comprising an isolated polynucleotide comprising "a" nucleic acid sequence as set forth in SEQ ID NO:23, wherein said construct further comprises a heterologous polynucleotide operably linked to the first polynucleotide and wherein the construct further comprises a nucleic acid encoding a peptide capable of directing transport of a polypeptide fused thereto into a subcellular compartment of a trichome, including wherein the compartment is a leucoplast. The use of the article "a" renders this recitation includes of fragments of SEQ ID NO:23 as small as dinucleotides.

Wan et al teach constructs encoding the pkg transit peptide fused to the cab protein, and they teach that this resulted in import into the leucoplasts (see page

31230, left column and Figure 5 A). They teach that *in vitro* transcription of each construct was initiated from the SP6 promoter (see page 31228, left column); and the SP6 promoter inherently comprises the sequence "ATTTAGGTGACACTATAG" as evidenced by the catalog page from Fermentas Life Sciences. Therefore, the SP6 promoter (which is a polynucleotide) comprises "TAT" which is "a" nucleic acid sequence of SEQ ID NO:23 (see bases 825-827 of SEQ ID NO:23).

14. No claim is allowed.

15. The nucleotide sequence of SEQ ID NO:23 is free of the prior art of record; therefore, if claims were amended to include the limitation that constructs and polynucleotides comprise the sequence of SEQ ID NO:23, then they would be free of the prior art of record.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cathy K. Worley whose telephone number is (571) 272-8784. The examiner is on a variable schedule but can normally be reached on M-F 10:00 - 4:00 with additional variable hours before 10:00 and after 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg, can be reached on (571) 272-0975.

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The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Cathy K. Worley/
Cathy K. Worley
Patent Examiner
Art Unit 1638

CKW